

*Patent*

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**Appendix 10**

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## Sanofi-aventis First Quarter of 2006: Sales growth of 9.6% on a reported basis and 4.9% on a comparable basis(1); 52.8% growth in adjusted EPS(1) and 19.8% excluding selected items(3)

PARIS, May 5 /PRNewswire-FirstCall/ -- The consolidated income statement for the first quarter of 2006 is provided in the appendices. 2006 first- quarter consolidated net income came to euro 1,512 million, compared to euro 531 million for the first quarter of 2005, after the post-tax impact of the accounting treatment of the Aventis acquisition and restructuring costs (euro 661 million in Q1 2006, euro 884 million in Q1 2005).

In order to give a better representation of our underlying economic performance, we have decided to publish and explain an adjusted consolidated income statement(1) for the first quarter of 2006, and compare it with an adjusted income statement for the first quarter of 2005. Adjusted net income for the first quarter of 2006 amounted to euro 2,173 million, against euro 1,415 million for the first quarter of 2005.

Unless otherwise indicated, all sales growth figures in this press release are stated on a comparable basis(1).

### FIRST QUARTER

Good sales growth despite the introduction of generics of 4 products(2)

-- Net sales: euro 7,035 million, up 4.9% (9.6% on a reported basis).

Excluding the impact of the introduction of generics of 4 products(2) in the United States in the second half of 2005, sales growth would have been 10.4%

-- Strong performance by the Vaccines business: net sales up 30.9%

-- Developed sales: up 6.8%

Adjusted EPS up 52.8% at euro 1.62 (vs. euro 1.06 for Q1 2005), and up 19.8% excluding selected items(3)

-- R&D expenses up by 13.3%

-- "Operating income - current" up 12.9% at euro 2,419 million

-- 53.6% growth in adjusted net income to euro 2,173 million

-- Selected items include a gain on the disposal of Exubera(R) of euro 384 million after tax

### LAUNCH OF PLAVIX IN JAPAN

Plavix(R) is due to be launched in Japan in May 2006.

### ACOMPLIA(R) RECOMMENDED FOR APPROVAL IN THE EUROPEAN UNION

for the following indication: " As an adjunct to diet and exercise for the treatment of obese patients (BMI greater than or equal to 30kg/m2), or overweight patients (BMI > 27 kg/m2) with associated risk factors, such as type 2 diabetes or dyslipidemia(4)

(1) Refer to the appendices for definitions of financial indicators

(2) Allegra(R), Amaryl(R), Arava(R) and DDAVP(R) in the United States

(3) See Appendix 5

(4) Importantly, statements in Section 5.1 of the Summary of Product Characteristics stipulate that half of the observed improvements in HbA1c, HDL cholesterol and triglycerides were beyond that expected

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from weight loss alone

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# FIRST-QUARTER RESULTS CONFIRM 2006 FULL-YEAR GUIDANCE

## 2006 first-quarter net sales

In the first quarter of 2006, sanofi-aventis posted net sales of euro 7,035 million, up 4.9%. Exchange rate movements had a favorable effect of 5.4 points, around two-thirds of which was due to the rise in the US dollar. Changes in Group structure had a negative effect of 0.7 of a point. After allowing for these impacts, reported-basis growth was 9.6%.

## Net sales by business segment

Net sales reported by sanofi-aventis comprise net sales generated by the pharmaceuticals business and net sales generated by the human vaccines business.

## Pharmaceuticals

First-quarter net sales for the pharmaceuticals business, which were significantly affected by the introduction of Allegra(R) generics in the United States in September 2005, rose by 3.3% to euro 6,523 million. Net sales of the top 15 products were up 7.6% at euro 4,265 million, representing 65.4% of pharmaceuticals net sales, against 62.8% for the same period in 2005. Excluding the impact of generics of Allegra(R) and Amaryl(R) in the United States, the top 15 products would have achieved growth of 15.4%.

euro million	Q1 2006 net sales	Change on a comparable basis
Lovenox(R)	624	+16.4%
Plavix(R)	580	+21.1%
Stilnox(R) /Ambien(R) /Ambien CR(TM)	441	+11.9%
Taxotere(R)	430	+11.1%
Eloxatin(R)	429	+15.0%
Lantus(R)	382	+42.0%
Copaxone(R)	263	+30.8%
Aprovel(R)	248	+15.9%
Tritace(R)	235	+2.2%
Allegra(R)	180	-56.4%
Amaryl(R)	121	-26.2%
Xatral(R)	94	+14.6%
Actonel(R)	89	+23.6%
Depakine(R)	78	+2.6%
Nasacort(R)	71	-4.1%
TOTAL TOP 15	4,265	+7.6%
TOTAL excluding impact of Allegra(R) and Amaryl(R) in the USA *	4,179	+15.4%

\* Excluding net sales of Allegra(R) and Amaryl(R) in the United States

First-quarter net sales of other pharmaceutical products were down 4.0% at euro 2,258 million. This fall was mainly due to the introduction of generics of BDAVP(R) (down 79.2%) and Arava(R) (down 96.8%) in the United States, and to price cuts. Excluding the impact of generics(5) of these two products, net sales of other pharmaceutical products would have declined by just 1.1%.

## Human vaccines

First-quarter consolidated net sales for the Human Vaccines business were up 30.9% at euro 512 million.

Sales were lifted by the success of Menactra(R) and Adacel(TM).

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Menactra(R), on sale in the United States since March 2005, achieved net sales of euro 53 million. Sales of Adacel(TM) (adult tetanus-diphtheria-whooping cough-Tdap booster), launched in the United States in July 2005, came to euro 31 million, and were helped by an extension of the vaccination recommendations issued by ACIP in the final quarter of 2005.

Sales of Decavac(R) (preservative-free adult booster against diphtheria and tetanus), launched in the United States in January 2005, came to euro 33 million.

2006 first-quarter sales of influenza vaccines were euro 72 million, a rise of 30.9%. Sales were boosted by a strong vaccination season in the southern hemisphere, and by an extension of the vaccination season in the United States. The first-quarter figures do not include any sales of H5N1 vaccines in the United States.

(5) Excluding U.S. net sales of Arava(R) and DDAVP(R)

euro million	Q1 2006 net sales	Change on a comparable basis
Polio/Whooping Cough/Hib Vaccines	185	+20.1%
Adult Booster Vaccines	81	+11.0%
Influenza Vaccines	72	+30.9%
Travel Vaccines	67	+81.1%
Meningitis/Pneumonia Vaccines	64	+128.6%
Other vaccines	43	-2.3%
TOTAL	512	+30.9%

Sanofi Pasteur MSD, the joint venture with Merck & Co in Europe, generated first-quarter sales of euro 144 million, up 12.5% on a reported basis. This strong growth was driven by fine performances from adult booster vaccines and the measles/mumps/rubella range. Excluding Hexavac(R), sales of which were suspended by the EMEA in September 2005, Sanofi Pasteur MSD would have posted sales growth of 35.3% on a reported basis.

These sales are not consolidated by sanofi-aventis.

#### Net sales by geographical region

euro million	Q1 2006 Net sales	Change on a comparable basis
Europe	3,168	+5.3%
United States	2,347	-0.5%
Other countries	1,520	+13.4%
TOTAL	7,035	+4.9%

In Europe, net sales advanced by 5.3%, with particularly good performances in the United Kingdom and Italy. In France, sales were adversely affected by new government measures (removal of products from reimbursement lists, price cuts, incentives designed to promote generics, and higher duties on prescription medicines), and this dragged down growth for the Europe region as a whole.

In the United States, net sales were down by 0.5%, a figure which includes the effect of generics competition on 4 products. Excluding the impact of these 4 products(2) on net sales, growth in the United States would have been 16.1%.

Growth in other countries reached 13.4%, with strong contributions coming from Latin America and Asia.

Developed sales

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Developed sales give an indication of the overall presence of sanofi-aventis products in the market. 2006 first-quarter developed sales reached euro 7,942 million, up 6.8%.

Developed sales of Plavix(R)/Iscover(R):

euro million	Q1 2006	Change on a comparable basis
Europe	425	+16.1%
United States	713	+27.3%
Other countries	165	+19.6%
TOTAL	1,303	+22.5%

First-quarter developed sales of Plavix(R) were up 22.5% to euro 1,303 million. In the United States, growth in total prescriptions (TRx) of Plavix(R) in the first quarter was 14.2%(6). Product sales in the United States were lifted by the launch late in 2005 of a new promotional campaign aimed at general practitioners, and by a stepping-up of product promotion in hospitals.

Plavix(R) is due to be launched in Japan in May 2006, as a treatment for the reduction of recurrence after ischemic cerebrovascular disorder.

The EMEA and the FDA are currently reviewing an application for Plavix(R) in acute ST-segment elevation myocardial infarction, based on the results of the COMMIT and CLARITY studies.

Developed sales of Aprovel(R)/Avapro(R)/Karvea(R):

euro million	Q1 2006	Change on comparable basis
Europe	213	+16.4%
United States	117	+36.0%
Other countries	84	+13.5%
TOTAL	414	+20.7%

First-quarter developed sales of Aprovel(R)/Avapro(R)/Karvea(R) totaled euro 414 million, a rise of 20.7%.

In the United States, first-quarter sales growth reached 36%, mainly due to lower rebates than in the first quarter of 2005. Total prescriptions rose by 6.0%(6) in the quarter.

(6) IMS NPA 3 channels-YTD 2006

#### Comments by product

#### Geographical split of consolidated net sales by product (TOP 15)

Q1 2006 net sales (euro million)	Europe	Change on a comparable basis	USA	Change on a comparable basis	Other countries	Change on a comparable basis
Lovenox(R)	173	+6.1%	391	+19.9%	60	+27.7%
Plavix(R)	411	+19.5%	61	+15.1%	108	+31.7%
Stilnox(R) / Ambien(R) / Ambien CR(TM)	24	-11.1%	394	+13.5%	23	+15.0%
Taxotere(R)	175	+17.4%	176	+0.6%	79	+25.4%
Eloxatin(R)	145	+13.3%	244	+11.4%	40	+53.8%
Lantus(R)	129	+48.3%	224	+34.1%	29	+93.3%
Copaxone(R)	66	+24.5%	184	+36.3%	13	-

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Aprovel(R)	200	+16.3%	-	-	48	+14.3%
Tritace(R)	135	-1.5%	4	+33.3%	96	+6.7%
Allegra(R)	14	+16.7%	83	-71.6%	83	-23.9%
Amaryl(R)	56	-8.2%	3	-94.0%	62	+17.0%
Xatral(R)	63	+12.5%	19	+18.8%	12	+20.0%
Actonel(R)	65	+25.0%	-	-	24	+20.0%
Depakine(R)	55	-1.8%	-	-	23	+15.0%
Nasacort(R)	10	-	53	-5.4%	8	-

Net sales of Lovenox(R), the leading low molecular weight heparin on the market, rose by 16.4% to euro 624 million. Growth of the product continues to be driven by the extension of its use in medical prophylaxis. In cardiology, the results of the ExTRACT study, presented at the American College of Cardiology in March 2006, will be filed in the second half of 2006 (prevention of recurrence or death in patients who have experienced myocardial infarction with ST-segment elevation).

Net sales of Ambien(R)/Ambien CR(TM) in the United States advanced by 13.5% to euro 394 million.

In Japan, developed sales of Myslee(R) came to euro 25 million, an increase of 9.6%.

Taxotere(R) recorded another excellent quarterly performance, both in Europe and the "Other countries" region. In the United States, the product is still facing a tough competitive environment.

In March 2006, Taxotere(R) was approved in the United States for advanced-stage stomach cancer in association with the standard treatment (cisplatin and 5-fluorouracil), and received a positive opinion from the Committee for Human Medicinal Products (CHMP) in Europe in the same indication. Filing for FDA and EMEA approval for Taxotere(R) as a neoadjuvant treatment of head and neck cancer is in progress.

Eloxatin(R), with net sales of euro 429 million, confirmed its status as the leading treatment for colorectal cancer. The take-up rate for the solution ready to use has reached 100% in France and 90% in the United States. This new formulation is currently being launched in a number of other European countries.

Lantus(R), the world's leading insulin brand, continues to record excellent performances, with net sales up 42.0% at euro 382 million. The results of the LANMET study, published in Diabetologia in March 2006, confirmed the benefits of Lantus in association with metformin over the combination of NPH insulin + metformin in patients with type II diabetes. Apidra(R), a new rapid-acting insulin analog for the treatment of type I and type II diabetes, and usable with OptiClick(R), has been on sale in the United States since the end of February 2006. Apidra(R) is an excellent complement to Lantus(R) in therapeutic regimens combining a basal insulin with a rapid-acting analog.

2006 first-quarter adjusted consolidated income statement (unaudited)

The adjusted consolidated income statement is presented in Appendix 3.

Refer to Appendix 1 for definitions of "adjusted net income", and to Appendix 4 for a reconciliation of the consolidated income statement to the adjusted consolidated income statement.

First quarter of 2006 (compared to adjusted first quarter of 2005)

Net sales generated by sanofi-aventis in the first quarter of 2006 were euro 7,035 million, up 9.6% on a reported basis.

Gross profit was euro 5,457 million, 10.0% higher than in the first quarter of 2005. The gross margin ratio rose by 0.3 of a point to 77.6%, compared to 77.3% for the first quarter of 2005, thanks to an increase of 18.9% in other revenues. Despite the impact of generics of Allegra(R),

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Amaryl(R), Arava(R) and DDAVP(R), the ratio of cost of sales to net sales was unchanged.

Research and development expenses were 13.3% up on the first quarter of 2005 at euro 1,046 million. This rise reflects increasing Phase III clinical trials activity in pharmaceuticals and greater investment in R&D in the vaccines business. Research and development expenses represented 14.9% of net sales, compared to 14.4% in the first quarter of 2005.

Selling and general expenses rose by 6.8% relative to the first quarter of 2005 to euro 2,050 million, representing 29.1% of net sales. Selling expenses rose sharply, but general expenses were lower year-on-year.

Operating income -- current was 12.9% higher at euro 2,419 million and represented 34.4% of net sales, a 1-point improvement on the 2005 first-quarter figure.

Other operating income and expenses came to euro 533 million, against euro 17 million in the first quarter of 2005. The 2006 figure includes gains on disposals of euro 550 million, including euro 461 million on Exubera(R) (euro 384 million after tax) and euro 45 million on the sale of the remaining 30% of the Animal Nutrition business.

Operating income was up 37.4% at euro 2,951 million.

Net financial expense came to euro 30 million, against euro 106 million in the first quarter of 2005. This substantial fall was mainly attributable to a reduction in total debt due to the cash flow generated by the Group. Interest expense on debt totaled euro 73 million, compared to euro 129 million in the first quarter of 2005.

Net financial expense also benefited from net gains on financial instruments (euro 37 million, vs. euro 10 million in the first quarter of 2005).

Income tax expense came to euro 832 million, against euro 650 million for the first quarter of 2005, giving an effective tax rate of 28.5%, against 31.8% for the first quarter of 2005. Excluding the gain on the disposal of Exubera(R), the effective tax rate for the quarter was 30.7% (2005: 31.8%).

The share of profit from associates was euro 181 million, against euro 107 million in the first quarter of 2005. The sharp rise in this item was due to strong growth in the Group's share of after-tax profits from the territories managed by BMS under the Plavix(R) and Avapro(R) alliance (euro 113 million, vs. euro 80 million in the first quarter of 2005), and to an increase in the contribution from Merial.

Minority interests amounted to euro 97 million, compared with euro 83 million in the first quarter of 2005. This line includes the share of pre-tax profits paid over to BMS from territories managed by sanofi-aventis (euro 94 million vs. euro 69 million in the first quarter of 2005).

Net income was 53.6% higher at euro 2,173 million.

Excluding selected items in the first quarter of 2005 and first quarter of 2006 (in 2006, these include the euro 384 million post-tax gain on the sale of Exubera(R), see Appendix 5), adjusted net income would have risen by 20.4%.

Earnings per share (EPS) was euro 1.62, 52.8% up on the 2005 first-quarter figure of euro 1.06, based on an average number of shares outstanding of 1,344.4 million in the first quarter of 2006 and 1,334.6 million in the first quarter of 2005.

Excluding selected items in the first quarter of 2005 and first quarter of 2006 (see Appendix 5), EPS would have risen by 19.8%.

Net debt, which stood at euro 9.9 billion at December 31, 2005, amounted to euro 8.1 billion at March 31, 2006. This figure takes account

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of the proceeds from the sale of Exubera(R) and the acquisition of a 24.9% interest in Zentiva.

## 2006 FULL-YEAR OUTLOOK

Our good first-quarter results confirm the 2006 full-year guidance announced on February 24, 2006:

Barring major adverse events, sanofi-aventis expects full-year adjusted EPS growth for 2006 to be in the region of 10%:

- despite the full-year impact of the availability of generics of Allegra(R), Amaryl(R), Arava(R) and DDAVP(R) in the United States;
- after taking account of the substantial launch costs of Plavix(R) in Japan and Rimonabant(R);
- assuming after-tax selected items(3) of euro 300 million, compared to after-tax selected items of euro 168 million in 2005;
- based on an exchange rate of euro 1:\$1.25, with sensitivity to the euro/dollar exchange rate estimated at 0.6% of growth for a 1-cent movement in the exchange rate.

## Recent events

February 28, 2006	Announcement of the U.S. launch of Apidra(R), a new rapid-acting insulin analog
March 12, 2006	Presentation to the American College of Cardiology of the results of the CHARISMA study
March 12, 2006	Presentation to the American College of Cardiology of the results of the TALISMAN study, demonstrating the benefits of NV1FGF in patients with critical ischemia of the lower limbs
March 14, 2006	Presentation to the ACC of the results of the EXTRACT study, demonstrating the superiority of a strategy using Lovenox(R) over a non-fractionated heparin in preventing recurrence of myocardial infarction
March 21, 2006	Announcement by sanofi-aventis and Bristol-Myers Squibb of agreement with Apotex to settle the patent infringement lawsuit between the parties in the U.S. District Court for the Southern District of New York. The lawsuit relates to the validity of a composition of matter patent for Plavix(R) (the '265 patent) in the United States. This agreement is subject to certain conditions, including antitrust review and clearance by the Federal Trade Commission and the State Attorneys General. There is a significant risk that antitrust clearance will not be obtained, in which case the proposed settlement would be terminated and the litigation would be reinstated in the same Court
March 23, 2006	Announcement of FDA approval for Taxotere(R) in advanced stomach cancer
March 24, 2006	Announcement of a positive opinion from the Committee for Human Medicinal Products (CHMP) for Taxotere(R) in metastatic stomach cancer
March 26, 2006	Announcement by Sanofi Pasteur MSD of a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for Zostavax(R), a vaccine against herpes zoster (shingles) and herpes zoster related postherpetic neuralgia



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March 27, 2006	Acquisition of a 24.87% interest in Zentiva
April 10, 2006	Court of Appeal rules in favor of sanofi-aventis in the Lovenox(R) patent infringement case in the United States
April 12, 2006	Announcement of the transfer to sanofi-aventis of all Japanese rights for rimonabant
April 28, 2006	Announcement of a positive opinion from the Committee for Human Medicinal Products (CHMP) for Acomplia(R) as an adjunct to diet and exercise for treatment of obese patients (BMI greater than or equal to 30kg/m2), or overweight patients (BMI > 27 kg/m2) with associated risk factors such as type 2 diabetes or dyslipidemia(4)
May 2, 2006	Announcement by Sanofi Pasteur MSD of a positive opinion from the Committee for Human Medicinal Products (CHMP) for Rotateg, a vaccine to prevent pediatric rotavirus gastroenteritis

## Financial calendar

May 31, 2006	Annual General Meeting
August 2, 2006	2006 second-quarter sales and results
October 31, 2006	2006 third-quarter sales and results

## About sanofi-aventis

Sanofi-aventis is the world's third largest pharmaceutical company, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine, and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY)

## Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expect," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2005. Other than as required by applicable law, sanofi-aventis does not

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undertake any obligation to update or revise any forward-looking information or statements.

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#### Appendices:

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- Appendix 2: 2006 first-quarter net sales by product
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- Appendix 4: 2006 first-quarter reconciliation of consolidated income statement to adjusted consolidated income statement (unaudited)
- Appendix 5: Trend in selected items of adjusted net income

#### Appendix 1: Explanatory notes

##### Comparable net sales

When we refer to the change in our sales on a "comparable" basis, we mean that we exclude the impact of exchange rate movements and changes in Group structure (acquisitions and divestments of interests in entities and rights to products, and changes in consolidation method for consolidated entities).

For any two periods, we exclude the impact of exchange rates by recalculating sales for the earlier period on the basis of exchange rates used in the later period. We exclude the impact of acquisitions by including sales for a portion of the prior period equal to the portion of the current period during which we owned the entity or product rights based on sales information we receive from the party from whom we make the acquisition.

Similarly, we exclude sales in the relevant portion of the prior period when we have sold an entity or rights to a product.

For a change in consolidation method, the prior period is recalculated on the basis of the method used for the current period.

Reconciliation of 2005 first-quarter reported net sales to 2005 first-quarter comparable net sales

euro million	Q1 2005
Q1 2005 reported net sales	6,417
Impact of changes in Group structure	(40)
Impact of exchange rates	330
Q1 2005 comparable net sales	6,707

##### Developed sales

When we refer to "developed sales" of a product, we mean consolidated net sales, excluding sales of products to our alliance partners, but including those that are made through our alliances and are not included in our consolidated net sales (with Bristol-Myers Squibb on Plavix(R)/Iscover(R) (clopidogrel) and Aprovel(R)/Avapro(R)/ Karvea(R) (irbesartan), and with Fujisawa on Stilnox(R)/Myslee(R)). Our alliance

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partners provide us with information regarding their sales in order to allow us to calculate developed sales.

We believe that developed sales are a useful measurement tool because they demonstrate the overall presence of our products in the market.

Reconciliation of net sales to developed sales:

euro million	Q1 2006
Net sales	7,035
Non-consolidated sales of Plavix(R)/Iscover(R), net of sales of product to BMS	723
Non-consolidated sales of Aprovel(R)/Avapro(R)/Karvea(R), net of sales of product to BMS	166
Non-consolidated sales of Stilnox(R)/Myslee(R), net of sales of product to Fujisawa	18
Developed sales	7,942

#### Adjusted net income

We define "adjusted net income" as accounting net income (determined under IFRS) adjusted to exclude (i) the material impacts of the application of purchase accounting to the acquisition of Aventis by sanofi-aventis and (ii) acquisition-related integration and restructuring costs. Sanofi-aventis believes that eliminating these impacts from net income gives investors a better understanding of the underlying economic performance of the combined Group.

The material impacts of the application of purchase accounting to the acquisition of Aventis by sanofi-aventis are as follows:

- Charges arising from the remeasurement of Aventis inventories at fair value, net of tax
- Amortization/impairment expense generated by the remeasurement of Aventis intangible assets, net of tax
- Any impairment charged against the goodwill arising on the acquisition

Sanofi-aventis also excludes from adjusted net income any integration and restructuring costs that are specific to the acquisition of Aventis by sanofi-aventis.

euro million	Q1 2006 Consolidated financial statements	Q1 2006 Adjusted consolidated financial statements (unaudited)
Net sales	7,035	7,035
Net income	1,512	2,173
Basic EPS	1.12	1.62

#### Appendix 2: 2006 first-quarter net sales by product

euro million	Q1 2006 net sales	Q1 2005 comparable net sales	Q1 2005 reported net sales
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Lovenox (R)	624	536	500
Plavix (R)	580	479	468
Stilnox (R) / Ambien (R) / Ambien CR (TM)	441	394	362
Taxotere (R)	430	387	365
Eloxatin (R)	429	373	350
Lantus (R)	382	269	252
Copaxone (R)	263	201	187
Aprovel (R)	248	214	209
Tritace (R)	235	230	218
Allegra (R)	180	413	386
Amaryl (R)	121	164	156
Xatral (R)	94	82	79
Actonel (R)	89	72	80
Depakine (R)	78	76	74
Nasacort (R)	71	74	67
TOTAL	4,265	3,964	3,753
Other products	2,258	2,352	2,304
TOTAL Pharmaceuticals	6,523	6,316	6,057
Vaccines	512	391	360
TOTAL net sales	7,035	6,707	6,417

Appendix 3: 2006 first-quarter adjusted consolidated financial statements  
(unaudited)

	Q1 2006 Adjusted consolidated income statement (unaudited)	as % of net sales	Q1 2005 Adjusted consolidated income statement (unaudited)	as % of net sales	% change
euro million					
Net sales	7,035	100.0%	6,417	100.0%	+9.6%
Other revenues	289	4.1%	243	3.8%	+18.9%
Cost of sales	(1,867)	26.5%	(1,697)	26.5%	+10.0%
Gross profit	5,457	77.6%	4,963	77.3%	+10.0%
Research and development expenses	(1,046)	14.9%	(923)	14.4%	+13.3%
Selling and general expenses	(2,050)	29.1%	(1,920)	29.9%	+6.8%
Other current operating income	119	-	77	-	+54.5%
Other current operating expenses	(28)	-	(27)	-	+3.7%
Amortization of intangibles	(33)	-	(27)	-	+22.2%
Operating income - current	2,419	34.4%	2,143	33.4%	+12.9%
Restructuring					

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costs	-	-	(13)	-	-
Impairment of PP&E and intangibles	(1)	-	-	-	-
Other operating income and expenses	533	-	17	-	-
Operating income	2,951	41.9%	2,147	33.5%	+37.4%
Financial expenses	(109)	-	(162)	-	-32.7%
Financial income	79	-	56	-	+41.1%
Income before tax and associates	2,921	41.5%	2,041	31.8%	+43.1%
Income tax expense	(832)	11.8%	(650)	10.1%	+28.0%
Effective tax rate	28.5%	-	31.8%	-	-
Share of profit/loss of associates	181	-	107	-	+69.2%
Net income before minority interests	2,270	32.3%	1,498	23.3%	+51.5%
Minority interests	(97)	-	(83)	-	+16.9%
Net income	2,173	30.9%	1,415	22.1%	+53.6%
Average number of shares outstanding (m)	1,344.4		1,334.6		
Earnings per share (in euros)	1.62		1.06		+52.8%

Appendix 4: 2006 first-quarter reconciliation of consolidated income statement to adjusted consolidated income statement (unaudited)

The adjustments to the income statement reflect the elimination of material impacts of the application of purchase accounting to the Aventis acquisition (euro 629 million net of deferred taxes, with no cash impact for the Group) and restructuring charges (euro 32 million net of tax), i.e. a total impact of euro 661 million.

euro million	Q1 2006 Consolidated (unaudited)	Adjustments	Q1 2006 Adjusted consolidated (unaudited)
Net sales	7,035		7,035
Other revenues	289		289
Cost of sales	(1,873)	6 (a)	(1,867)
Gross profit	5,451	6	5,457
Research and development expenses	(1,046)		(1,046)
Selling and general expenses	(2,050)		(2,050)
Other current operating income	119		119
Other current operating expenses	(28)		(28)
Amortization of intangibles	(1,000)	967 (b)	(33)
Operating income - current	1,446	973	2,419
Restructuring costs	(48)	48 (c)	-

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Impairment of PP&E and intangibles	(1)		(1)
Other operating income and expenses	533		533
Operating income	1,930	1,021	2,951
Financial expenses	(109)		(109)
Financial income	79		79
Income before tax and associates	1,900	1,021	2,921
Income tax expense	(451)	(381) (d)	(832)
Share of profit/loss of associates	160	21 (e)	181
Net income before minority interests	1,609	661	2,270
Minority interests	(97)		(97)
Net income	1,512	661	2,173
Average number of shares outstanding (m)	1,344.4		1,344.4
Earnings per share (in euros)	1.12	0.50	1.62

The material impacts of the application of purchase accounting to the Aventis acquisition and of restructuring charges on the 2006 first-quarter consolidated income statement are as follows:

- (a) A charge of euro 6 million arising from the workdown of acquired inventories remeasured at fair value. This adjustment has no cash impact on the Group.
- (b) An amortization charge of euro 967 million against intangible assets. This adjustment has no cash impact on the Group.
- (c) A pre-tax restructuring charge of euro 48 million.
- (d) The tax impact primarily comprises:
  - (1) Deferred taxes of euro 365 million generated primarily by the amortization charge of euro 967 million taken against intangible assets and by the euro 6 million charge arising from the workdown of acquired inventories remeasured at fair value. This adjustment has no cash impact on the Group.
  - (2) A tax saving of euro 16 million related to the euro 48 million of restructuring charges.
- (e) In "Share of profit/loss from associates", a charge of euro 21 million corresponding to the amortization of intangibles (net of tax) and the workdown of acquired inventories. This adjustment has no cash impact on the Group.

#### Appendix 5: Trend in selected items of adjusted net income

euro million	Q1 2006	Q1 2005
Restructuring costs (Aventis pre-acquisition programs)	-	(13)
Net gains on disposals (including euro 461 million pre-tax gain on Exubera(R))	550	7
Provisions for investment portfolio, financial instruments and other items	30	1

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TOTAL before tax	580	(5)
TOTAL after tax	466	(3)

## REMINDER

8.00 am CET - WEBCAST  
& CONFERENCE CALL (English)

The 1st quarter 2006 sales and earnings will be reviewed at 8.00 am (Paris time) by Mr. Hanspeter Spek, Executive Vice-President, Pharmaceutical Operations and Mr. Jean-Claude Leroy, Executive Vice-President, CFO. The slides will be available on <http://www.sanofi-aventis.com>. This presentation will be followed by a Q&A session.

## CALL-IN NUMBERS

The conference will also be available by telephone via the following numbers:

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*Patent*

U.S. Ser. No.: 10/054,638

Response to the Office Action mailed 12 December 2007

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**Appendix 11**

This citation refers to an entire chapter of a book. Applicant will submit this reference if the examiner is unable to obtain the reference.



## Chapter 34

# Meningococcal Vaccines

DAN M. GRANOFF\* • IAN M. FEAVERS • RAY BORROW



### History

Meningococci (*Neisseria meningitidis*) are fastidious gram-negative endotoxin-containing organisms. The pathogen is unique among causes of bacterial meningitis for its ability to cause epidemic disease. Epidemics of meningococcal meningitis were first described in Geneva, Switzerland, by Vieusseux in 1805,<sup>1</sup> and in Medfield, Massachusetts, by Danielson and Mann in 1806.<sup>2</sup> Weichselbaum was the first to culture meningococcus from patients with meningitis in 1887.<sup>3</sup> Meningococcal epidemics in sub-Saharan Africa have been recognized for more than 100 years.<sup>4</sup>

### Importance of Meningococcal Disease

Meningococci cause serious disease worldwide. In sub-Saharan Africa, large epidemics occur every 5 to 10 years. In the United States and Europe, the last major meningococcal epidemics were in the 1940s. However, the organism remains the most common cause of bacterial meningitis in children and young adults. Each year there are approximately 3000 cases of meningococcal disease reported in the United States<sup>5</sup> and 7700 cases in Western Europe.<sup>6</sup> Approximately half of the cases are meningitis. In New Zealand, an epidemic of group B meningococcal disease has been ongoing for more than a decade.<sup>7</sup>

Before the advent of antibiotics, the mortality rate from meningococcal disease was 70% to 85%. Specific antiserum therapy was introduced early in the 20th century and lowered the risk of death to approximately 30%. Today, despite an increased understanding of the pathogenesis of meningococcal disease and the availability of appropriate treatments, the overall mortality rate remains at 10% to 15%.<sup>8,9</sup>

\*D.M.G. was supported, in part, by grants RO1 AI 45642 and AI46464 from the National Institutes of Allergy and Infectious Disease, National Institutes of Health. This chapter incorporates some material written by Martha Lepow, Bradley Perkins, Patricia Hughes, and Jan Poolman, authors of the chapter on meningococcal vaccines that appeared in the third edition of *Vaccines*.

Recent research is increasing our understanding of why some individuals who acquire the organism develop invasive meningococcal disease, whereas hundreds of others acquiring the same organism do not.<sup>9</sup> However, much remains to be learned about the complex interactions between the organism and the host that affect the development and outcome of meningococcal infection. Other baffling questions relate to the geographic distribution of strains causing disease in different populations. Why are group A strains responsible for most epidemic disease in sub-Saharan Africa, and what factors have led to the virtual disappearance of group A strains from the United States and Europe for more than 50 years? Also, what factors have led to the emergence of group Y disease in the United States or group B disease in New Zealand in the 1990s, or to group W135 strains in Sub-Saharan Africa in 2001 and 2002?<sup>10,11</sup>

### Background

#### Clinical Description and Presentation

The dominant clinical features of meningococcal disease are fever, rash, and meningitis, but the initial signs and symptoms may be indistinguishable from those of other severe bacterial, rickettsial, or viral infections. Sixty percent of patients with meningococcal disease will have experienced symptoms for less than 24 hours when they present to the hospital.

The most common clinical presentation is acute bacterial meningitis. Older children and adults typically present with abrupt onset of fever, headache, photophobia, and complaints of aching all over. Seizures occur in approximately 20% of patients. Signs of altered consciousness (hyperactivity or lethargy) are prominent. Nuchal rigidity is a common sign except in infants, in whom a more gradual onset of fever, poor feeding, and lethargy are the typical presenting complaints, and a bulging fontanel may be the major clue of central nervous system involvement. A rash is present in the majority of cases of meningococcal disease, consisting of typical petechiae or larger purpuric lesions that usually are most apparent on the chest, upper arms, and axillae.<sup>8</sup> Maculopapular rashes also are common and may occur in the absence of petechiae.

Ten to 20% of patients with meningococcal disease present with severe sepsis or meningococcemia ("purpura fulminans"). Meningitis may be absent, but the organism is